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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,991	05/08/2007	Andrew Jonathan Humberstone	025217-0147	1892

22428 7590 06/25/2008

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EXAMINER	
BOSWORTH, KAMI A	

ART UNIT	PAPER NUMBER
4177	

MAIL DATE	DELIVERY MODE
06/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,991	HUMBERSTONE ET AL.	
	Examiner	Art Unit	
	KAMI A. BOSWORTH	4177	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/7/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: On page 18, line 9, the membrane is incorrectly referenced with the number 3; however, the membrane should be referenced with the number 2.

Appropriate correction is required.

2. The disclosure is objected to because of the following informalities: On page 20, lines 21 and 23, US Pat No. 6,229,900 is referred to; however, the examiner believes the applicant meant to refer to US Pat No. 6,299,900 as disclosed in the IDS.

Appropriate correction is required.

Claim Objections

3. Claim 3 is objected to because of the following informalities: In claim 3, “application site” lacks proper antecedent basis. The examiner assumes the “application site” is meant to be the “administration site” as presented in claim 1 and suggests this be changed. Appropriate correction is required.

4. Claim 5 is objected to because of the following informalities: “the reservoir” lacks proper antecedent basis. It is suggested, “the reservoir” be changed to “a reservoir”. Appropriate correction is required.

5. Claims 13 and 14 are objected to because of the following informalities: In claims 13 and 14, “the group” lacks proper antecedent basis. It is suggested, “the group” be changed to "a group”. Appropriate correction is required.

6. Claims 2, 4, 7, 12, and 18 are objected to because of the following informalities: In claims 2, 4, 7, 12, and 18, “the membrane device” lacks proper antecedent basis. The examiner assumed the "membrane device" is meant to be the "device" as presented in claim 1 and suggests this be changed. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5, 11, 12, 16, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Church (PG PUB 2002/0128579).

9. Re claim 1, Church discloses a method for inhibiting the percutaneous absorption of a physiologically active agent (Para 12, Line 3) topically applied to a transdermal administration site of a subject, the method including the step of applying to skin of the subject at the transdermal administration site (Para 28, Line 10), a device 1 (Fig 1) comprising a membrane 3 (Fig 1) for contacting the skin of the subject coated on the skin contacting side thereof with a layer of an adhesive 7 (Fig 1).

10. Re claim 2, Church discloses that the membrane device is applied to the transdermal administration site of a subject who has received adverse side effects from the physiologically active agent (Para 12, Lines 3-4), wherein a dose of physiologically active agent transferred to the blood stream is thereby reduced (Para 9, Lines 1-3).

11. Re claim 3, Church discloses that the membrane is applied to the whole of the transdermal administration site (Para 28, Lines 14-16).

12. Re claim 4, Church discloses that the physiologically active agent is administered so as to form a reservoir (resulting from a sting or bite; Para 28, Line 17) of the physiologically active agent in the skin and the application of said membrane device results in the physiologically active agent being extracted from the skin to significantly reduce the total dose of drug which would otherwise be administered transdermally (Para 12, Line 3).

13. Re claim 5, Church discloses a method for removal of physiologically active agent (Para 12, Line 3) from a reservoir (resulting from a sting or bite; Para 28, Line 17) thereof within the skin of a subject following transdermal administration of the physiologically active agent to a site on the skin of the subject the method including the step of applying a device 1 (Fig 1) comprising a membrane 3 (Fig 1) to the site of transdermal administration (Para 28, Lines 14-16) of the pharmaceutically active agent.

14. Re claim 11, Church discloses that an overdose of physiologically active agent (resulting from a sting or bite; Para 28, Line 17) has been topically applied to the site of skin prior to the membrane being applied thereto.

15. Re claim 12, Church discloses an assembly 1 (Fig 1) further comprising at least one layer 3 (non-body contacting side of porous envelope lies between said reservoir and a backing layer, remote from side applied to the skin; Para 28, Lines 4-7) on the side of said membrane remote from the side applied to the skin and wherein a reservoir of solvent (charcoal composition mixed with gel or gum; Para 28, Lines 4-6, Para 34,

Para 35) is provided between said at least one layer and said membrane wherein said active agent is at least partially soluble in the solvent.

16. Re claim 16, Church discloses a method of reducing the effect of overdose via transdermal administration of a physiologically active agent (Para 12, Line 3) to a site of skin (Para 28, Line 17) of a subject to form a reservoir (resulting from a sting or bite; Para 28, Line 17) of physiologically active agent in the skin the method comprising providing a membrane assembly 1 (Fig 1) for contacting the site of skin the membrane assembly comprising

(a) selectively permeable membrane 3 (Fig 1) for making contact with the skin to allow ingress of physiologically active agent and provided with an adhesive layer 7 (Fig 1) on the skin side thereof,

(b) a backing layer 5 (Fig 1) and

(c) a reservoir of solvent (charcoal composition mixed with gel or gum; Para 28, Lines 4-6, Para 34, Para 35) between the backing layer and membrane wherein the physiologically active agent is at least partly soluble in the solvent and preferably

(d) a solvent impermeable layer 3 (non-body contacting side of porous envelope lies between said membrane and the backing layer, remote from the adhesive layer on the skin side thereof; Para 28, Lines 4-7) adjacent the side of said membrane remote from the adhesive;

and applying the adhesive layer of the membrane assembly to the site of transdermal administration wherein the physiologically active agent is extracted from the skin into the membrane assembly (Para 12, Line 3).

17. Re claim 17, Church discloses that the physiologically active agent comprises insecticides (Para 12, Line 4).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claim 9 is rejected under 35 U.S.C. 103(a) as being obvious over Church.

20. Church discloses that the membrane is between 1/32 and 1/16 inches thick; however, Church does not disclose that the membrane is less than 2 mm thick. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the membrane less than 2 mm thick, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

21. Claims 6-8, 13, 14, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Church in view of Sun et al. (PG PUB 2002/0115957).

22. Re claim 6, Church discloses all the claimed features except that the membrane is coated with a layer of adhesive on the skin contacting side.

Sun et al., however, teaches that the membrane 516 (Fig 5c) is coated with a layer of an adhesive 509 (Fig 5c) on the skin contacting side 504 (Fig 5c) of the membrane for adhering the membrane to the site of transdermal administration.

Therefore, it would have been obvious to one skilled in the art at the time of invention to modify Church to include a layer of adhesive coating on the skin contacting side of the membrane, as taught by Sun et al., for the purpose of adhering the membrane to the site of transdermal administration.

23. Re claims 7 and 18, Church discloses all the claimed features except the membrane device comprising an elastic, occlusive, or semi-permeable layer selected from polyurethane polymers, ethylene vinyl acetate copolymers, hydrocolloid, or cellulosic membranes.

Sun et al., however, teaches a membrane device comprising of a semi-permeable layer 516 (Fig 5c) made of cellulosic membranes (Para 70, Lines 1-2) for the purpose of controlling transmission of the active agent.

Therefore, it would have been obvious to one skilled in the art at the time of invention to modify Church to include a semi-permeable cellulosic membrane, as taught by Sun et al., for the purpose of selectively controlling the adsorption of the active agent.

24. Re claims 8 and 19, Church discloses all the claimed features except the adhesive layer is permeable to the physiologically active agent and is selected from the group consisting of acrylics, polyethylenes, polysiloxanes, polyisobutylenes, polyacrylates, polyurethanes, plasticized ethylene vinyl acetate copolymers and tacky rubbers.

Sun et al., however, teaches that the adhesive layer 509 (Fig 5c) is permeable to the physiologically active agent and is made of polyisobutylenes (Para 45, Lines 5-6) for the purpose of allowing active agent to pass.

Therefore, it would have been obvious to one skilled in the art at the time of invention to modify Church to include a permeable layer of adhesive coating made of polyisobutylene, as taught by Sun et al., for the purpose of allowing active agent to pass from the body to the device.

25. Re claims 13 and 14, Church discloses all the claimed features except that the solvent is selected from a group consisting of alcohols, alkanes, ethers, ketones, chlorinated hydrocarbons and nitriles and is selected from a group consisting of ethanol and its derivatives, methanol, chloroform, isopropyl alcohol and mixture of two or more thereof.

Sun et al., however, teaches that the solvent is isopropyl alcohol (Para 58, Lines 16-21) for the purpose of driving the transdermal administration of active agent.

Therefore, it would have been obvious to one skilled in the art at the time of invention to modify Church to include an isopropryl alcohol solvent, as taught by Sun et al., for the purpose of driving the transdermal adsorption of the active agent from the skin.

26. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Church in view of Warren et al. (PG PUB 2003/0082219).

27. Re claim 10, Church discloses all the claimed features except where the membrane is applied within 24 hours of transdermal application of the active agent.

Warren et al., however, teaches that the membrane is applied to the site of transdermal administration within 24 hours of transdermal application of the physiologically active agent (Claim 20) for the purpose of being most effective by stopping migration of the active agent as soon as possible.

Therefore, it would have been obvious to one skilled in the art at the time of invention to modify Church to include the application of the membrane within 24 hours of active agent exposure, as taught by Warren et al., for the purpose of stopping migration of the active agent as soon as possible.

28. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Church in view of Luther et al. (US Pat 6,238,693).

29. Re claim 15, Church discloses all the claimed features except where the membrane remains adhered to the skin for at least 12 hours.

Luther et al., however, teaches that the membrane remains adhered to the skin at the site of transdermal administration for a period of at least 12 hours (Col 3, Lines 9-11) for the purpose of ensuring full transmission of active agent between the patch and the body.

Therefore, it would have been obvious to one skilled in the art at the time of invention to modify Church to include the application of the membrane for at least 12 hours, as taught by Luther et al., for the purpose of removing the most active agent possible from the body.

Conclusion

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Eckenhoff et al. (US Pat 4,756,314), Juhasz et al. (US Pat 4,715,857), Peck (US Pat 4,960,467), Schoendorfer (US Pat 5,944,662), Schoendorfer et al. (US Pat 5,899,856), and Stanley et al. (US Pat 5,291,887) disclose dermal extraction patches with reservoirs and membranes. Bourdeau (US Pat 5,465,508) and Carey (US Pat 5,840,072) disclose extraction patches to limit adverse side effects.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAMI A. BOSWORTH whose telephone number is (571)270-5414. The examiner can normally be reached on Monday - Thursday, 8:00 am to 4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Quang D. Thanh can be reached on (571)272-4982. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. A. B./
Examiner, Art Unit 4177

/Terrell L Mckinnon/
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